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CLAIMS amended based on Article 34

1. (Amended) A medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing and granulating the following ingredients:

- (1) the medicament with an unpleasant taste,
- (2) methylcellulose, and
- (3) mannitol,

wherein the amount of the methylcellulose is about 0.8 to about 10 parts by weight per 1 part by weight of the medicament with an unpleasant taste.

2. (Deleted)

3. (Deleted)

4. The medicament-containing particle according to claim 1 wherein the amount of the methylcellulose is about 0.8 to about 5 parts by weight per 1 part by weight of the medicament with an unpleasant taste.

5. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about 0.3 to about 50 parts by weight per 1 part by weight of the

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methylcellulose.

6. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about
5 0.5 to about 12 parts by weight per 1 part by weight of the methylcellulose.

7. (Amended) The medicament-containing particle according to claim 1 or 4 wherein the amount of the mannitol is about
10 0.7 to about 7.5 parts by weight per 1 part by weight of the methylcellulose.

8. (Amended) The medicament-containing particle according to any one of claim 1 and claims 4 - 7 wherein the mannitol
15 is D-mannitol.

9. (Amended) The medicament-containing particle according to any one of claim 1 and claims 4 - 8 wherein the medicament with an unpleasant taste is 4-amino-5-chloro-2-
20 ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]-benzamide or a pharmaceutically acceptable salt thereof.

10. (Amended) The medicament-containing particle according to claim 1 which is obtainable by mixing and granulating
25 the following ingredients:

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(1) (\pm) -4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]benzamide citrate dihydrate as a medicament,

(2) methylcellulose, and

5 (3) D-mannitol,

wherein the amount of the methylcellulose is about 0.8 to about 10 parts by weight per 1 part by weight of (\pm) -4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]methyl]benzamide citrate, and

10 the amount of the D-mannitol is about 0.3 to about 50 parts by weight per 1 part by weight of the methylcellulose.

11. (Amended) A solid preparation comprising the medicament-containing particle set forth in any one of
15 claim 1 and claims 4 - 10 and other pharmaceutically acceptable ingredients for pharmaceutical preparation.

12. The solid preparation according to claim 11 which is a tablet-like preparation or a granule-like preparation.

20

13. The solid preparation according to claim 12 wherein the tablet-like preparation is in the form of a tablet or a pill.

25 14. The solid preparation according to claim 12 wherein

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the granule-like preparation is in the form of a granule, a fine granule or a powder.

15. The solid preparation according to any one of claims
5 11 - 14 which is an intrabuccally rapidly disintegrating preparation.

16. The solid preparation according to claims 15 wherein
10 the intrabuccally rapidly disintegrating preparation is in the form of a tablet.

17. The solid preparation according to claim 15 wherein
the intrabuccally rapidly disintegrating preparation is a granule-like preparation.

15

18. The intrabuccally rapidly disintegrating preparation
set forth in any one of claims 15 - 17 which is
characterized by the following properties:

(i) disintegrating within 40 seconds on a tongue of a
20 healthy adult with his mouth closed and without chewing,

(ii) dissolving at a substantial dissolution rate of
85% or more after 15 minutes according to the dissolution
test described in the Japanese Pharmacopoeia XIV [using
Method 2 (50 rpm) for tablets or Method 1 (50 rpm) for
25 granule-like preparation, resolution medium : 900 mL of

water], and

(iii) not substantially feeling an unpleasant taste on setting the preparation in buccal cavity.

5

19. A composition for preparing the intrabuccally rapidly disintegrating preparation set forth in claim 15, which comprises

10 a medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing and granulating the medicament with an unpleasant taste, methylcellulose and mannitol;

an excipient; and

a disintegrator.

15

20. (Amended) A process for preparing a medicament-containing particle wherein an unpleasant taste of the medicament is alleviated, which is obtainable by mixing (1) the medicament with an unpleasant taste, (2) 20 methylcellulose whose amount is about 0.8 to about 10 parts by weight per 1 part by weight of the medicament with an unpleasant taste and (3) mannitol, and granulating the mixture with water or a water-containing solvent.

25 21. A commercial package which comprises the solid

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preparation set forth in claim 11 comprising 4-amino-5-chloro-2-ethoxy-N-[[4-(4-fluorobenzyl)-2-morpholinyl]-methyl]benzamide or a pharmaceutically acceptable salt thereof as a medicament with an unpleasant taste; and a
5 written matter as to the solid preparation,
including a description on the outside of the package or in the written matter inside the package which intends that the solid preparation can/should be used for promoting gastrointestinal motility, improving postgastrectomy
10 condition, or preventing/treating gastroesophageal reflux disease (GERD).

請 求 の 範 囲

1. (補正後) 下記の成分:

(1) 不快な味を有する薬物、

5 (2) メチルセルロースおよび

(3) マンニトール

を混合し粒子化してなる薬物の不快な味を低減した薬物含有粒子であって、不快な味を有する薬物1重量部に対して、メチルセルロースを約0.8～約10重量部程度の割合で含む薬物含有粒子。

10 2. (削除)

3. (削除)

4. 不快な味を有する薬物1重量部に対して、メチルセルロースを約0.8～約5重量部程度の割合で含む請求項1記載の薬物含有粒子。

15 5. (補正後) メチルセルロース1重量部に対して、マンニトールを約0.3～約50重量部程度の割合で含む請求項1または4に記載の薬物含有粒子。

6. (補正後) メチルセルロース1重量部に対して、マンニトールを約0.5～約12重量部程度の割合で含む請求項1または4に記載の薬物含有粒子。

7. (補正後) メチルセルロース1重量部に対して、マンニトールを約0.7～約7.5重量部程度の割合で含む請求項1または4に記載の薬物含有粒子。

20 8. (補正後) マンニトールがD-マンニトールである請求項1又は4～7のいずれかに記載の薬物含有粒子。

9. (補正後) 不快な味を有する薬物が、4-アミノ-5-クロロ-2-エトキシ-N-[[4-(4-フルオロベンジル)-2-モルホリニル]メチル]ベンズアミドまたはその生理学的に許容される塩である請求項1又は4～8のいずれかに記載の薬物含有粒子。

25 10. (補正後) (1) (±)-4-アミノ-5-クロロ-2-エトキシ-N-[[4-(4-フルオロベンジル)-2-モルホリニル]メチル]ベンズアミドのクエン酸塩2水和物、

(2) メチルセルロースおよび

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(3) D-マンニトール

を混合し粒子化してなる請求項1に記載の薬物含有粒子であって、

(±) -4-アミノ-5-クロロ-2-エトキシ-N-[[4-(4-フルオロベンジル)-2-モルホリニル]メチル]ベンズアミドのクエン酸塩 1重量部に対してメチルセルロースを約0.8～約10重量部程度、メチルセルロース 1重量部に対してD-マンニトールを約0.3～約50重量部程度の割合で含む薬物含有粒子。

11. (補正後) 請求項1又は4～10のいずれかに記載の薬物含有粒子と薬学的に許容される製剤化成分を含む固形製剤。

12. 固形製剤が錠剤状製剤または粒状製剤である請求項11に記載の固形製剤。

13. 錠剤状製剤が錠剤または丸剤である請求項12に記載の固形製剤。

14. 粒状製剤が、顆粒剤、細粒剤または散剤である請求項12に記載の固形製剤。

15. 固形製剤が口腔内速崩壊製剤である請求項11～14のいずれかに記載の固形製剤。

16. 口腔内速崩壊製剤が錠剤である請求項15に記載の固形製剤。

17. 口腔内速崩壊製剤が粒状製剤である請求項15に記載の固形製剤。

18. 次の特性を備えることを特徴とする請求項15～17のいずれかに記載の口腔内速崩壊製剤：

(i) 本製剤を健常成人の舌のうえに置き、閉口のまま噛まない状態において40秒以内に崩壊し、

(ii) 日本薬局方第14改正に記載の溶出試験（錠剤においては第2法（50回転／分）、粒状製剤においては第1法（50回転／分）、溶媒：水900ml）において、15分後の溶出率が実質的に85%以上であり、

(iii) 本製剤を口に含むとき、実質的に不快な味を感じない。

19. (補正後) 請求項15に記載の口腔内速崩壊製剤を製造するための組成物であって、不快な味を有する薬物、メチルセルロース及びマンニトールを混合し粒子化してなる不快な味を低減した薬物含有粒子、賦形剤、並びに崩壊剤を含有する組成物。

20. (補正後) (1) 不快な味を有する薬物、(2) 不快な味を有する薬物1重量部に対して、約0.8～約10重量部程度の量のメチルセルロースおよび(3) マンニトールを混合し、水または含水溶媒を用いて粒子化することを特徴とする薬物の不快な味を低減した薬物含有粒子の製造方法。

- 5 21. 不快な味を有する薬物として4-アミノ-5-クロロ-2-エトキシ-N-[[4-(4-フルオロベンジル)-2-モルホリニル]メチル]ベンズアミドまたはその生理学的に許容される塩を含む請求項11に記載の固形製剤及び当該固形製剤に関する記載物を含む商業パッケージであって、当該固形製剤を消化管運動機能促進、胃切除後症状の改善又は胃食道逆流症(GERD)の予防若しくは
- 10 治療に使用することができる又は使用すべきである旨の記載を、該パッケージ上又は該パッケージ内の記載物を含む商業パッケージ。

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